

## **REMARKS**

By way of the present amendment, the specification has been amended to update the status of cited patent applications and correct obvious typographical errors. Further, independent claims 1, 12, 22, 32, 42, 52, and 62 have been amended, and dependent claims 4, 14, 24, 34, 44, 54, and 64; 5, 15, 25, 35, 45, 55, and 65; 6, 16, 26, 36, 46, 56, and 66; 9, 19, 29, 39, 49, 59 and 69 have been amended. Claims 7-11, 17-21, 27-31, 37-41, 47-51, 57-61, and 67-71 have been cancelled. New dependent claims 72-113 have been added. Upon entry of the amendment, claims 1-6, 12-16, 22-26, 32-36, 42-46, 52-56, 62-66 and 72-113 will be pending. No new matter enters by way this amendment.

### **I. Sequence Listing**

Applicants thank the Examiner for indication that the Sequence Listing filed September 8, 2004 has been approved by the Office.

### **II. Objections to the Specification**

The specification has been objected to for purportedly containing informalities. Office Action at page 2. At the request of the Examiner, Applicants have amended the cited paragraphs to reflect the current status of the respective U.S. non-provisional patent applications. In addition, Applicants have corrected the misspelling of "naphthylalanine" on page 21, line 3. In light of these amendments, Applicant respectfully requests withdrawal of the objection to the specification.

### **III. Rejections Under 35 U.S.C. § 112, Second Paragraph**

Claims 4, 9, 14, 19, 24, 29, 34, 39, 44, 49, 54, 59, 64, and 69 stand rejected under 35 U.S.C. §112, second paragraph for allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Withdrawal of these rejections is respectfully requested for at least the reasons which follow.

Claims 4, 14, 24, 34, 44, 54, and 64 are allegedly indefinite due to the recitation of the phrase "GLP-1 is selected from the group consisting of GLP-1 (7-36)NH<sub>2</sub>, GLP-4(7-37), GLP-1(9-36) and exendin-4." Applicants have amended claims 4, 14, 24, 34, 44, 54, and 64 to recite

“said peptide compounds.” Accordingly, it is submitted that the claims comply with 35 U.S.C. § 112, second paragraph, and withdrawal of this rejection is respectfully requested.

Claims 9, 19, 29, 39, 49, 59 and 69 are allegedly indefinite because it is allegedly “not clear if the PPAR inhibitors are to be limited to the specific examples recited in the parenthetical phrases.” In addition, these claims are also objected to for the recitation of trademarks. Although Applicants disagree that such terms are unclear, to facilitate prosecution, Applicants have cancelled claims 9, 19, 29, 39, 49, 59 and 69. As such, withdrawal of this rejection is respectfully requested.

#### **IV. Non-Statutory Double Patenting Rejection**

Claims 1-71 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-18 of copending Application No. 10/317,126. Applicants note that the rejection is provisional because no allegedly conflicting claims have been patented. Upon an indication of allowable subject matter, a terminal disclaimer with regard to any issued claims in the ‘126 Application will be filed. At that time, withdrawal of this rejection is respectfully requested.

#### **V. Entitlement under 35 U.S.C. § 120 to the Benefit of Parent Application**

The Examiner alleges that “claims 1-71 are not deemed to be entitled under 35 U.S.C. 120 to the benefit of the filing date of parent application 10/317,126.

In this regard, the Examiner’s attention is directed to the claims as currently amended. Applicants’ respectfully submit that the claims are fully supported under 35 U.S.C. § 112, first paragraph by the disclosure of parent application 10/317,126, as well as in provisional Application Serial No. 60/350,395 from which the parent application claims priority. At a minimum, see, e.g., the disclosure at paragraph [0031] of US 2004/0029784 A1. Taken in combination with the entirety of the disclosure of the parent applications, paragraph [0031] provides more than adequate disclosure of the subject matter of the present claims.

Further, Applicants respectfully traverse the Examiner’s characterization of the disclosure of the parent applications, particularly with regard to exendin compounds. At a minimum, the parent applications disclose exendin peptides obtainable from Gila monster venom, which were known in the art at the time of filing. Taken in combination with the entirety of the disclosure of

the parent applications, particularly with regard to agonists of the GLP-1 receptor, the parent applications disclose much more than merely “exendin-4 in its unamidated form,” as alleged by the Examiner. At the time the parent applications were filed, it was known that exendin-4, as it occurred *in vivo*, was an amidated peptide, as was GLP-1.

In any event, whatever else the parent applications do disclose, the presently pending claims are clearly supported under 35 U.S.C. § 112, first paragraph by the disclosure of parent applications. As such, it is respectfully submitted that, at a minimum, the pending independent claims are entitled to the benefit of the filing date of the parent applications.

#### **VI. Statement of Common Ownership**

Further, with regard to the Examiner’s comment regarding Applicants’ alleged obligation to advise regarding inventorship and invention date of claims not commonly owned at the time a later invention was made, Applicants’ do not fully understand the Examiner’s request. However, as discussed above, the presently pending independent claims are entitled to the benefit of the filing date of the parent applications. As such, the parent applications do not constitute prior art with regard to such claims, and Applicants’ have no obligation to make an assertion of common ownership at the time of invention of such claims.

However, even assuming *arguendo* that certain dependent claims are not entitled to the benefit of the filing date of the parent application, then Applicants hereby assert that to the extent there are any claims directed to any subject matter which is not entitled to the filing date of the parent applications, then such inventions were commonly owned with the parent applications at the time the later inventions were made. As such, it is submitted that the parent applications may not form the basis of a rejection under 35 U.S.C. § 103(a) with regard to any such claims.

#### **VII. Rejections Under 35 U.S.C. § 102**

##### **A. U.S. Patent Application Publication 2004/0029784**

Claims 1-71 stand rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent Application Publication 2004/0029784 (hereinafter the “’784 Publication”), which is the publication of U.S. Patent Application Serial No. 10/317,126. This rejection is respectfully traversed. As discussed above, the presently pending claims are entitled to the benefit of the

filing date of the parent applications, and as such, the '784 Publication does not constitute prior art under 35 USC § 102(e). Further, to the extent that, *arguendo*, any limitations of any dependent claims are not entitled to the filing date of the parent application, then likewise, the parent application does not anticipate such subject matter. Accordingly, withdrawal of this rejection is respectfully requested.

B. Knudsen

Claims 1-6, 9, 11-16, 19, and 21 stand rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Knudsen (U.S. Patent Application Publication 2004/0180824). This rejection is respectfully traversed, and to the extent that it applies to the amended claims, reconsideration is requested for at least the reasons that follow. Again, as discussed above, the presently pending claims are entitled to the benefit of the filing date of the parent application. As such, Knudsen does not constitute prior art under 35 USC § 102(e).

C. Fryburg

Claims 1-4, 12-14, and 22-24 stand rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Fryburg, *et al.* (U.S. Patent No. 6,610,746). This rejection is respectfully traversed, reconsideration is requested for at least the reasons that follow.

The Examiner alleges that Fryburg teaches "treating patients having or at risk of having polycystic ovary syndrome by administering a combination of a sulfonylurea and/or a non-sulfonylurea K<sup>+</sup> ATP channel blocker, a cAMP phosphodiesterase type 3 inhibitor, and another agent." wherein the agent may be "GLP-1(7-37) or GLP-1 (7-36)-NH<sub>2</sub>." Office Action at page 7.

Applicants respectfully submit that the method disclosed in Fryburg *et al.* fails to disclose all of the limitations of the present claims. "It is axiomatic that for prior art to anticipate under § 102 it has to meet every element of the claimed invention." *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986). Initially, Fryburg fails to specifically teach, disclose or suggest that a peptide compound that binds to or activates a GLP-1 receptor is specifically usefully in the treatment of PCOS, other than as one of any number of possible optional "additional agents" in a number of possible combination treatments. Moreover, GLP-1(7-37) or GLP-1 (7-36)-NH<sub>2</sub> are merely mentioned in an extensive listing of known agents

for the treatment of non-insulin dependent diabetes mellitus, insulin resistance, impaired glucose tolerance, Syndrome X, hyperglycemia, polycystic ovarian syndrome, cataracts, or any of the diabetic complications such as neuropathy, nephropathy, retinopathy, or cardiomyopathy. The listing of known agents includes insulin, insulin analogs, mefformin, phenformin, buformin, fatty acid oxidation inhibitors, clomoxir,  $\alpha$ -glucosidase inhibitors, lipid-lowering agents, antiobesity agents amylin antagonists, glucagon antagonists, *etc.* Nowhere does Fryburg specifically mention, or even suggest that GLP-1(7-37) or GLP-1 (7-36)-NH<sub>2</sub> may be useful to treat PCOS, or which additional agent, if any, among the long list of known agents is specifically useful to treat PCOS.

As such, whatever else Fryburg does teach, it does not teach administering an amount of a peptide compound to a subject exhibiting at least one symptom of PCOS, wherein the peptide compound is capable of binding to or activating a GLP-1 receptor *in vivo*, and wherein the amount is effective to treat the at least one symptom of PCOS. As each independent claim requires at least such administration, it is submitted that Fryburg does not anticipate each and every limitation of the pending claims.

Accordingly, for at least the foregoing reasons, the rejection of claims 1-7 and 22-24 under 35 U.S.C. § 102(b) is traversed. Reconsideration and withdrawal of this rejection are respectfully requested.

#### **VIII. Rejection under 35 U.S.C. § 103(a)**

Claims 5, 15, and 25 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Fryburg *et al.* (U.S. Patent No. 6,610,746). Office Action at page 7. Applicants respectfully disagree and traverse for at least the reasons that follow.

To establish a *prima facie* case of obviousness, the prior art reference (or references when combined) must teach or suggest all of the claim limitations. There must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. The teaching or suggestion to make the claimed combination must be found in the prior art, and not be based on applicant's disclosure. *See* M.P.E.P. §§2143.01 and 2143.03.

As argued above, whatever else Fryburg *et al.* does disclose, it does not disclose, teach or even suggest that GLP-1 (7-37) or GLP-1 (7-36)-NH<sub>2</sub> may be useful to specifically treat PCOS. As such, the cited reference does not teach or suggest the claimed methods. For at least the foregoing reasons, Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 103(a) of claims 5, 15, and 25.

#### **IX. Additional Cited Art**

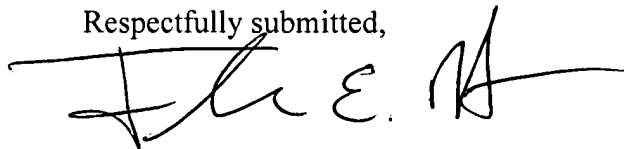
Applicants note that the Examiner has cited Odaka *et al.* (U.S. Patent No. 6,329,403) as art of interest. Applicants acknowledge and thank the Examiner for the indication that Odaka *et al.* is not deemed to teach or suggest the instant claimed invention.

In addition, Applicants note also that the Examiner has cited Mogensen *et al.* (U.S. Patent No. 6,569,901) as art of interest. Applicants also thank the Examiner for noting that the reference is duplicative of the references already cited in the Office Action.

#### **Conclusion**

In view of the above, each of the presently pending claims is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections of the claims, and to pass this application to issue. The Examiner is encouraged to contact the undersigned at (202) 942-5085 should any additional information be necessary for allowance.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'D. R. Marsh', with a long horizontal flourish extending to the right.

David R. Marsh (Reg. No. 41,408)  
Milan M. Vinnola (Reg. No. 45,979)  
Thomas E. Holsten (Reg. No. 46,098)

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ARNOLD & PORTER LLP  
555 Twelfth Street, NW  
Washington, D.C. 20004  
(202) 942-5000 telephone  
(202) 942-5999 facsimile